IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	:	
Nicholas Paul MacMillan et al.	:	
Serial No.	:	Art Unit:
Filed: concurrently herewith	:	Examiner:
For: VALVES AND SUCTION CATHETER ASSEMBLIES	:	Atty Docket: 0119/0032

SUBMISSION OF PRIORITY DOCUMENTS

Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Attached hereto please find certified copies of applicants' priority application as follows:

United Kingdom Patent Application No. 0304457.5 filed February 27, 2003
United Kingdom Patent Application No. 0323511.6 filed October 8, 2003

Applicants request the benefit of said February 27, 2003 and October 8, 2003 filing dates for priority purposes pursuant to the provisions of 35 USC 119.

Respectfully submitted,

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Date: Jan 29 2004

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

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27FEB03 E788236-1 C26047
P01/7700 0.00-0304457.5

THE PATENT OFFICE
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27 FEB 2003
NEWPORT

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The Patent Office
Cardiff Road
Newport
Gwent NP9 1RH

1. Your reference — 0300040

2. Patent application number *(The Patent Office will fill in this part)* — 0304457.5 — 27 FEB 2003

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

SMITHS GROUP PLC
765 FINCHLEY ROAD
LONDON
NW11 8DS

Patents ADP number *(if you know it)* — 8032310001

If the applicant is a corporate body, give the country/state of its incorporation — GB

4. Title of the invention

VALVES AND SUCTION CATHETER ASSEMBLIES

5. Name of your agent *(if you have one)*

J. M. FLINT

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

765 FINCHLEY ROAD
LONDON
NW11 8DS

Patents ADP number *(if you know it)* — 1063304001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

YES

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	8 ✓
Claim(s)	
Abstract	✓
Drawing(s)	3+3 ✓

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature J Flint Date 26 FEB 2003

12. Name and daytime telephone number of person to contact in the United Kingdom J.M. FLINT 020 8457 8220

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VALVES AND SUCTION CATHETER ASSEMBLIES

This invention relates to valves and suction catheter assemblies.

Closed system suction catheter assemblies are used to remove secretions from within a tracheal tube or the respiratory passages of a patient. The assembly comprises a manifold at one end with a sliding seal through which a suction catheter can be advanced and withdrawn. A flexible envelope is joined at one end to the manifold and encloses the catheter along its length. The other end of the envelope and the catheter is joined with a rear end component including a suction control valve and a connector. The connector connects the catheter to a suction source and the valve enables the clinician to control the suction applied by the catheter.

Suction catheter assemblies are disposable so it is important that they are of low cost. The cost of providing the valve contributes a significant part to the overall cost of the assembly so it is important that this can be made at low cost whilst also operating efficiently with low risk of blockage and leakage. Various forms of suction control valve have been described previously such as in US 5269728, US 5300043, US 4569344, US 4638539, US 4836199, US 4872579, US 5277177 and US 5215522. There are also applications other than closed system suction catheters where similar forms of valves are required.

It is an object of the present invention to provide an alternative valve and a suction catheter assembly including such a valve.

According to one aspect of the present invention there is provided a valve for controlling flow of fluid along a passage defined by a first bore and a second bore opening into the first bore through an aperture, a valve member slidable along a third bore aligned with the first bore, the valve member having sealing means and being movable from a first position where the sealing means is on a side of the aperture remote from the first bore such as to allow fluid flow between the first and second bores to a second position on an opposite side of the aperture to block flow of fluid between the first and second bores.

The valve preferably includes resilient means urging the valve member to the second position. The resilient means is preferably of a non-ferrous material. The valve member preferably includes first and second annular sealing means, arranged such that when the valve member is in the second position the first and second sealing means are on opposite sides of the aperture. The valve preferably includes a user-actuable member located to one side of the valve member by which the valve member can be displaced. The valve member may have a forward tip angled to direct flow between the two bore. Alternatively, the end of the valve member may be arranged to engage a tapered valve seat in the second position.

According to another aspect of the present invention there is provided a suction catheter assembly including a suction catheter and a valve according to the above one aspect of the invention connected at a machine end of the catheter.

According to a further aspect of the present invention there is provided a suction catheter assembly of the kind including a suction catheter, a suction control valve towards the rear end of the assembly by which suction applied to the catheter can be controlled, a patient

end manifold by which the assembly is connected with a tracheal tube, and a flexible envelope extending between the manifold and the control valve around the catheter, the suction control valve having a user-actuable member for controlling opening and closing of the valve that is movable substantially axially of the catheter from a rear, open position to a forward, closed position.

The bore through the suction catheter is preferably substantially aligned with the first bore in the valve.

A closed system suction catheter assembly including a suction control valve, according to the present invention, will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a side elevation view of the assembly;

Figure 2 is an enlarged cross-sectional view of the valve;

Figure 3 is a plan view of the valve;

Figure 4 is a perspective view of the valve member;

Figure 5 is an enlarged cross-sectional view of a part of a modified valve; and

Figure 6 is an enlarged side elevation view of a part of a modified valve slider.

With reference first to Figure 1, the assembly includes a forward or patient end manifold coupling 1 having a first port 10 adapted to connect to a standard 15mm tracheal connector of the kind fitted to the machine end of a tracheal tube. At the opposite end of the coupling 1 and aligned with the first port 10 is a second port 11 containing a wiping seal 12 through which the suction catheter 20 can be extended and withdrawn. The coupling 1 has two further ports 13 and 14 aligned with one another and extending at right angles to the first and second ports 10 and 11. These further ports are connected to two limbs of a patient ventilation system (not shown). Swivels may be provided on these ports.

The suction catheter 20 is flexible, typically being about 500mm long and having an external diameter of about 5mm. The rear, machine end 21 of the catheter is connected to a suction control valve 30 and its forward end 22 locates just forwardly of the seal 12 in the patient end coupling 1. A flexible envelope 23 extends around the catheter 20 being joined at its forward end to the coupling 1 and at its rear end to the suction control valve 30. The flexible nature of the envelope 23 is such as to enable the catheter 20 to be manipulated through the envelope to allow the catheter to be pushed forwardly or pulled rearwardly through the seal. The length of the envelope 23 is chosen to prevent the forward end 22 of the catheter 20 being pulled through the seal 12. As so far described, the assembly is conventional.

With reference now also to Figures 2 to 4, the suction control valve 30 differs from previous valves. It has an outer housing 31 of a rigid, transparent plastics material, such as polycarbonate, having a main body portion 32 extending axially of the catheter 20 and an

outlet connection arm 33 inclined downwardly at an angle of about 30°. The rear end 21 of the suction catheter 20 is bonded onto a short spigot 34 within an outer collar 35 at the forward end of the body portion 32. The rear end of the envelope 23 is bonded onto the outside of the collar 35 within an outer ring 135 fitted over the collar. The interior of the spigot 34 communicates with a fluid passageway 36 through valve 30 provided by a first bore 37 extending axially within the main body portion 32 and a second bore 38 extending through the outlet connection arm 33 and opening into the first bore through an aperture 4. The bore 37 through the main body portion 32 continues rearwardly of the aperture 4 via a third bore 39 and opens into a recess 40 of increased height. The recess 40 opens via a slot 41 into a channel 42 extending forwardly axially along the upper surface of the main body portion 32 and surrounded on three sides by a peripheral wall 43. The angle of the outlet connection arm 33 is chosen to enable the valve 30 to be held comfortably in the hand, with the fingers under the arm and the thumb on top of the main body portion 32. The lower, free end of the arm 33 is tapered and stepped to enable tubing 2 extending to the suction source 3 to be pushed onto the arm and retained securely in position.

The housing 31 contains a user-actuable valve member 50, which is moulded of a coloured plastics material, which may be coded for different sizes. The valve member 50 has a sealing portion 51 provided by a rod-shape piston 52 of circular section with a forward face 53 inclined forwardly at an angle of about 30°. The piston 52 carries two annular sealing rings 54 and 55 located in annular recesses 56 and 57 around the outside of the piston and positioned towards its opposite ends. The rear end of the piston 52 connects via a reduced diameter stem 58 with a rear portion 59 having a cylindrical recess 60 extending axially and opening at its rear. A short beam 61 projects upwardly from the rear portion 59 to the

underside of a cantilevered slider 62. The slider 62 takes the form of a plate, most clearly seen in Figure 4, which is wider than the piston 52 and has a laterally-extending, ribbed projection 63 of semi-cylindrical shape on its upper surface close to the forward end of the slider. The slider 62 extends forwardly along the channel 42 in the upper surface of the housing 31so that the projection 63 is accessible to the user. Instead of a projection, a surface formation for engagement by the thumb could be provided by a ribbed concave recess 163 on a slider 162, as shown in Figure 6. The housing 31 also contains a resilient member in the form of a helical spring 64, preferably of a non-ferrous material, such as a hard plastics material, for example, polycarbonate. The spring 64 is aligned axially of the first and third bores 37 and 39 and is located between the rear, right-hand end of the valve member 50 and the inside of the housing 31. More particularly, the forward, left-hand end of the spring 64 is located in the recess 60 in the valve member 50 and its rear, right-hand end is secured around a short peg 65, extending in an annular recess 66 around the peg.

The solid lines in Figure 2 show the valve 30 with the valve member 50 held open by gripping the projection 63 on the slider 62 with the thumb and pushing it rearwardly against the resilience of the spring 64, to its maximum extent. In this position it will be seen that the forward end 53 of the piston 52 is located at the rear edge of the aperture 4 and its forward seal 54 is located to the rear of this. Suction applied by the suction source 3 to the second bore 38 is communicated to the main, first bore 37 via the aperture 4 and, therefore, to the bore of the suction catheter 20 so that secretions or the like can be removed when the tip 22 of the catheter is advanced into the tracheal tube. The angled tip 53 of the piston 52 helps direct flow of materials into the second bore 38. When the slider 62 is released, the spring 64 pushes the valve member 50 forwardly to its maximum extent (as shown by the broken lines

in Figure 2) where the two seals 54 and 55 are located on opposite sides of the aperture 4. The forward seal 54 prevents suction being communicated to the first bore 37 and the suction catheter 20; the rear seal 55 isolates the user from any contamination.

When the valve 30 is open there is no impediment to flow between the two bores 37 and 38, compared with some previous valves where there is a risk that the valve member might cause solid materials carried in the fluid to block the valve. The open flow path makes it easier to clean, thereby enabling the assembly to be used for longer periods with low risk of infection. The sliding action needed to open the valve 50 minimizes the risk of inadvertent actuation compared with some previous valves actuated by a press-down action. Because of this, there is no need to lock the valve to prevent inadvertent actuation, thereby ensuring that the valve is always available for operation. This is an advantage because an inexperienced user may not know immediately how to release a locked valve, resulting in delay in its operation. The axial sliding motion needed to operate the valve encourages the user to pull back the catheter in a straighter fashion when withdrawing from the tracheal tube. This reduces the risk of kinking the catheter. The construction of the valve enables it to be gas sterilized in its natural, closed state because gas can penetrate all parts of the valve through its bores 37 and 38 and the slot 41. The transparent housing 31 enables the user to confirm the absence of blockages within the valve. Its simple construction enables the valve to be produced at low cost and with a low weight, thereby minimizing forces applied to the tracheal tube. The valve can be used with single lumen catheters, as described, or with double lumen catheters where the additional lumen is for supply of an irrigating fluid.

The valve could be modified in various ways such as shown in Figure 5 where components equivalent to those shown in Figure 2 and 6 are given the same number with the addition of 100. The sealing portion 151 is integrally moulded with two sealing rings 154 and 155 from a resilient material such as a latex-free rubber. The forward end 153 of the sealing portion 151 is square to the axis rather than being angled and its dimensions are chosen so that its circular, peripheral edge 190 bears against a tapered, frusto-conical valve seat 191 formed at the forward end of the bore 137 when the valve member 150 is in its forward, rest position. The contact of the sealing portion 151 on the valve seat 191 provides an additional seal to those provided by the annular sealing rings 154 and 155, to prevent flow of fluid along the bore 137.

The valve is not limited to use with suction catheters but could be used in other applications for controlling flow of fluid.

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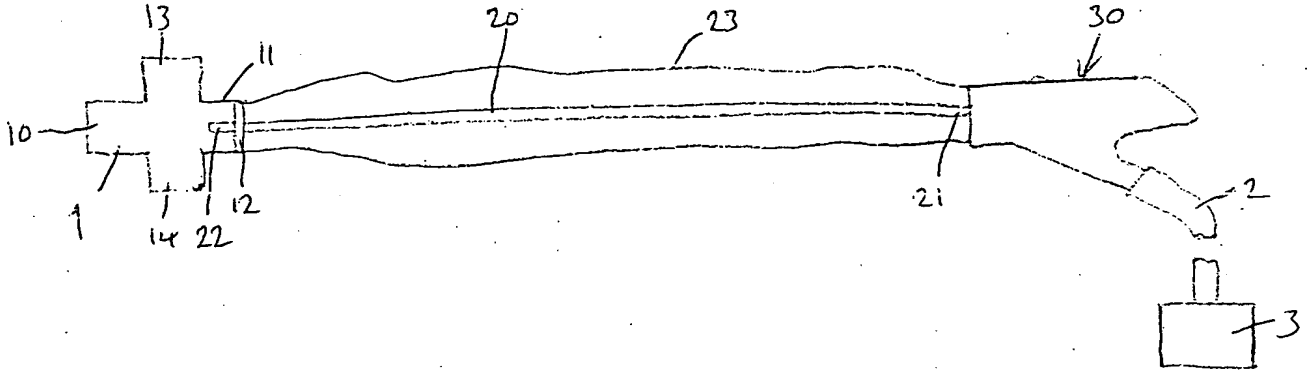

FIG. 1

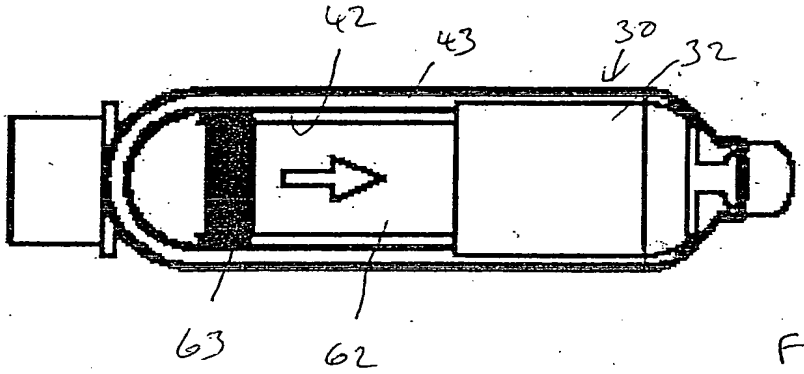

FIG. 3

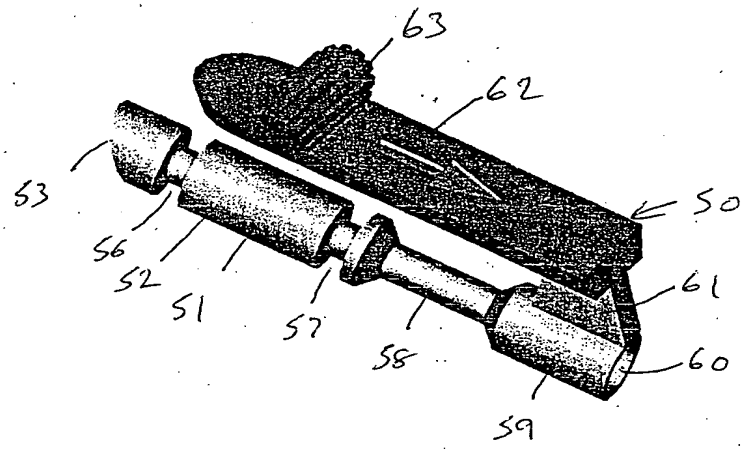

FIG. 4

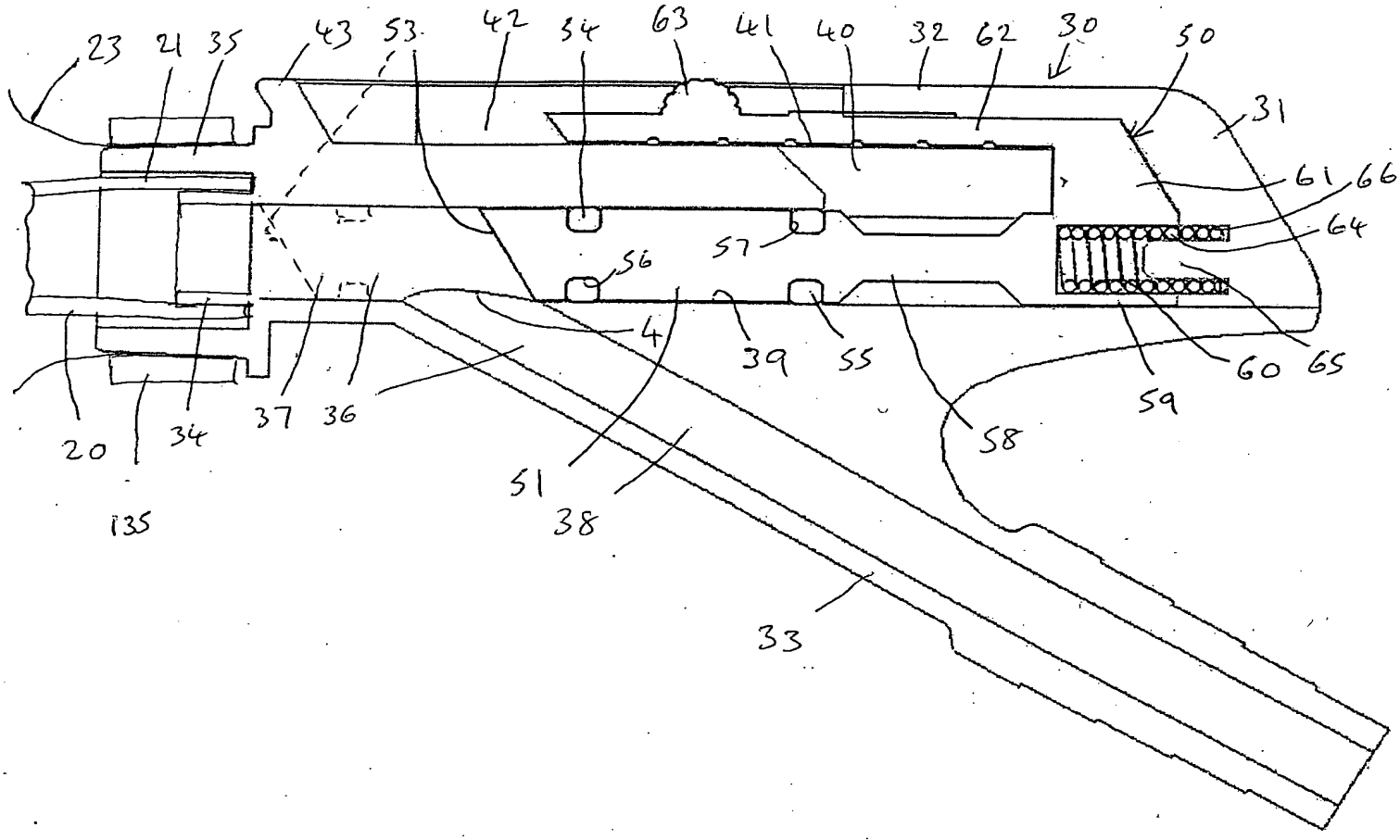
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FIG. 2

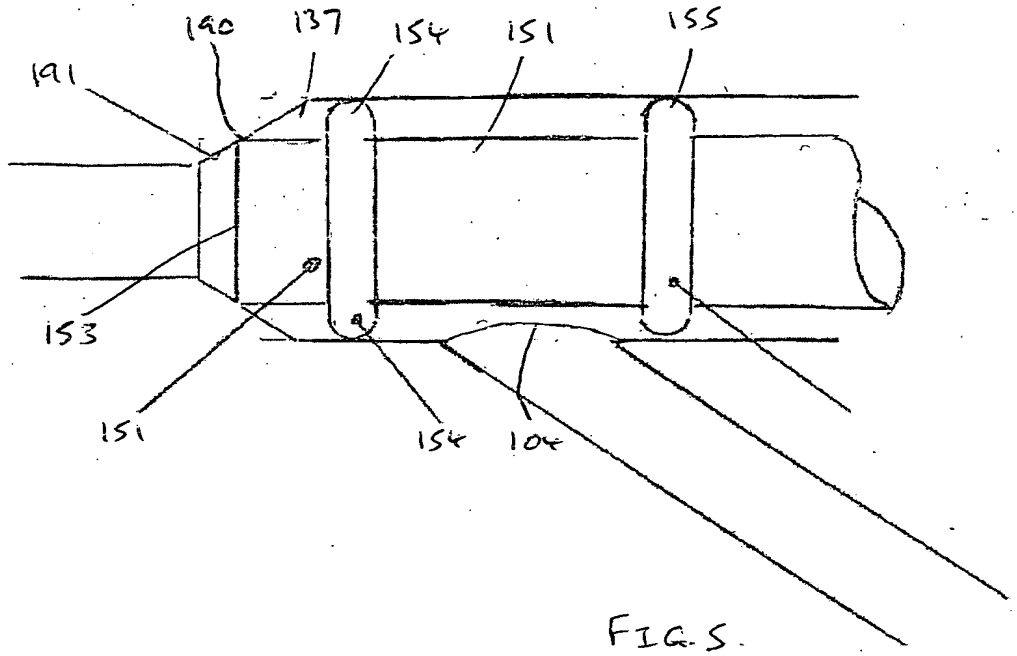

FIG. 5.

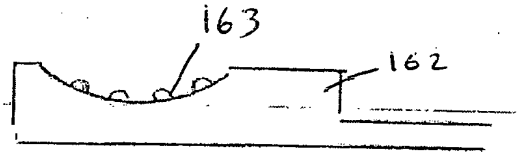

FIG. 6